

AMENDED IN SENATE APRIL 21, 2014

AMENDED IN SENATE APRIL 1, 2014

**SENATE BILL**

**No. 1014**

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**Introduced by Senator Jackson**  
**(Principal coauthor: Senator Leno)**  
**(Coauthors: Senators Evans, Hancock, Liu, and Pavley)**  
(Coauthors: Assembly Members Ammiano and Williams)

February 13, 2014

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An act to add Section 4068.1 to the Business and Professions Code, to amend Section 117700 of, and to add Section 117670.1 to, the Health and Safety Code, and to add Article 3.4 (commencing with Section 47120) to Chapter 1 of Part 7 of Division 30 of the Public Resources Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 1014, as amended, Jackson. Pharmaceutical waste: home generated.

(1) The Department of Resources Recycling and Recovery was required, pursuant to provisions repealed on January 1, 2013, to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of drug waste.

~~This bill would enact the Home-Generated Pharmaceutical Waste Collection Disposal Act and would define terms for purposes of the act. The bill would require a producer of covered pharmaceuticals to submit to the Department of Resources Recycling and Recovery, by July 1, 2015, except as specified, a product stewardship plan and would authorize one or more producers to submit a plan or designate a stewardship organization to act as an agent on behalf of the producers to submit a plan. The bill would require the stewardship plan to contain~~

~~specified elements with regard to the collection and disposal of home-generated pharmaceutical waste, including provisions for the payment of all administrative and operational fees associated with the product stewardship program.~~

~~The bill would specify procedures for the approval of the plan by the department and would require a producer, group of producers, or stewardship organization operating a stewardship program to take specified actions with regard to the disposal of home-generated pharmaceutical waste and promoting product stewardship programs to consumers, pharmacists, retailers of covered pharmaceuticals, and health care practitioners.~~

~~The bill would require a producer, group of producers, or stewardship organization operating a product stewardship program to prepare and submit to the department an annual written report describing the program's activities during the previous calendar year by July 1, 2016, or at a later date as approved by the department, and on or before July 1 annually thereafter.~~

~~The bill would authorize the department to adopt regulations to implement the act and would require the department to adopt regulations to provide for the appropriate management of consolidated home-generated pharmaceutical waste, to establish a schedule of fees to be charged to cover the department's costs of administering and enforcing the act, and to adopt a schedule setting the amounts of administrative civil penalties that the department would be authorized to impose. The bill would require a producer, group of producers, or a stewardship organization submitting a plan to the department to pay the fees set by the department and would require the department to deposit the fees into the Home-Generated Pharmaceutical Waste Program Account, which the bill would create in the Integrated Waste Management Fund. The department would be authorized to expend the fees, upon appropriation by the Legislature, to administer and enforce the act.~~

~~The bill would authorize the department to issue an administrative order to, or impose a civil penalty upon, a producer who is in violation of the act or a regulation adopted pursuant to the act. The bill would require the department to deposit the penalties into the Home-Generated Pharmaceutical Waste Penalty Account, which the bill would create in the Integrated Waste Management Fund, and would authorize the department to expend the moneys in that account, upon appropriation by the Legislature, to enforce the act.~~

*This bill would require the department to adopt regulations to authorize a participant to establish a program to collect and properly dispose of home-generated pharmaceutical waste, based upon the model guidelines developed by the department pursuant to those repealed provisions and to include specified requirements and provisions in those regulations. The bill would require an entity that elects to implement a home-generated pharmaceutical waste collection program to comply with the requirements specified in those regulations and would deem a participant operating a program in accordance with those regulations to be in compliance with all state laws and regulations concerning the handling, management, and disposal of home-generated pharmaceutical waste.*

(2) The Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, including pharmaceutical waste, as defined. Existing law defines the term medical waste and excludes certain types of waste from that definition.

This bill would define the term “home-generated pharmaceutical waste” for purposes of that act. The bill would exclude, from the definition of medical waste, home-generated pharmaceutical waste that is handled by a collection and disposal program operating in accordance with the ~~act~~ *regulations* specified above. ~~This exclusion would not become operative until the Secretary of State posts a notice regarding the effective date of the regulations that the department is required to adopt pursuant to that act.~~

(3) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy establishments by the California State Board of Pharmacy, and makes a knowing violation of that law a misdemeanor.

The bill would also authorize a pharmacy to accept the return of home-generated pharmaceutical waste from a consumer, consistent with specified federal laws. Because a knowing violation of this provision would be a crime, the bill would impose a state-mandated local program.

(4) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1     *SECTION 1. Section 4068.1 is added to the Business and*  
2     *Professions Code, to read:*

3     *4068.1. A pharmacy may accept the return of home-generated*  
4     *pharmaceutical waste, as defined in Section 117670.1 of the Health*  
5     *and Safety Code, from a consumer, consistent with the Federal*  
6     *Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) and*  
7     *the federal Controlled Substances Act (21 U.S.C. Sec. 801 et seq.).*

8     *SEC. 2. Section 117670.1 is added to the Health and Safety*  
9     *Code, to read:*

10    *117670.1. "Home-generated pharmaceutical waste" means a*  
11    *prescription or over-the-counter human or veterinary*  
12    *home-generated pharmaceutical, including, but not limited to, a*  
13    *home-generated pharmaceutical as defined in Section 109925 or*  
14    *in Section 321(g)(1) of Title 21 of the United States Code, that is*  
15    *a waste, as defined in Section 25124, derived from a household,*  
16    *including, but not limited to, a multifamily residence or household.*

17    *SEC. 3. Section 117700 of the Health and Safety Code is*  
18    *amended to read:*

19    117700. Medical waste does not include any of the following:

20    (a) Waste generated in food processing or biotechnology that  
21    does not contain an infectious agent as defined in Section 117675.

22    (b) Waste generated in biotechnology that does not contain  
23    human blood or blood products or animal blood or blood products  
24    suspected of being contaminated with infectious agents known to  
25    be communicable to humans.

26    (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,  
27    or vomitus, unless it contains fluid blood, as provided in  
28    subdivision (d) of Section 117635.

29    (d) Waste which is not biohazardous, such as paper towels,  
30    paper products, articles containing nonfluid blood, and other  
31    medical solid waste products commonly found in the facilities of  
32    medical waste generators.

33    (e) Hazardous waste, radioactive waste, or household waste,  
34    including, but not limited to, home-generated sharps waste, as  
35    defined in Section 117671.

36    (f) Waste generated from normal and legal veterinarian,  
37    agricultural, and animal livestock management practices on a farm  
38    or ranch.

1 (g) *Home-generated pharmaceutical waste, including, but not*  
2 *limited to, consolidated home-generated pharmaceutical waste,*  
3 *that is handled by a collection and disposal program operating in*  
4 *accordance with the regulations adopted by the Department of*  
5 *Resources Recycling and Recovery pursuant to Article 3.4*  
6 *(commencing with Section 47120) of Chapter 1 of Part 7 of*  
7 *Division 30 of the Public Resources Code.*

8 SEC. 4. Article 3.4 (commencing with Section 47120) is added  
9 to Chapter 1 of Part 7 of Division 30 of the Public Resources Code,  
10 to read:

11  
12 *Article 3.4. Home-Generated Pharmaceutical Waste Collection*  
13 *and Disposal*  
14

15 47120. For the purposes of this article, the following terms  
16 have the following meanings, unless the context clearly requires  
17 otherwise:

18 (a) “Consumer” means an individual purchaser or owner of a  
19 pharmaceutical. “Consumer” does not include a business,  
20 corporation, limited partnership, or an entity involved in a  
21 wholesale transaction between a distributor and retailer.

22 (b) “Entity” means a state or local public agency, pharmacy,  
23 veterinarian clinic, or other office or facility that provides medical  
24 services.

25 (c) “Home-generated pharmaceutical waste” has the same  
26 meaning as defined in Section 117670.1 of the Health and Safety  
27 Code, and includes all of the following:

28 (1) Articles recognized in the official United States  
29 Pharmacopoeia, the official National Formulary, the official  
30 Homeopathic Pharmacopoeia of the United States, or any  
31 supplement of the formulary or those pharmacopoeias.

32 (2) Articles intended for use in the diagnosis, cure, mitigation,  
33 treatment, or prevention of disease in humans or other animals.

34 (3) Articles, excluding food, intended to affect the structure or  
35 function of the body of humans or other animals.

36 (4) Articles intended for use as a component of an article  
37 specified in paragraph (1), (2), or (3).

38 (d) “Participant” means an entity that the department deems  
39 appropriate for implementing and evaluating a program in

1 *accordance with the regulations adopted pursuant to this article*  
2 *and that chooses to participate.*

3 *(e) "Sale" includes, but is not limited to, transactions conducted*  
4 *through sales outlets, catalogs, or the Internet, or any other similar*  
5 *electronic means, but does not include a sale that is a wholesale*  
6 *transaction with a distributor or retailer.*

7 *47121. (a) The department shall adopt regulations authorizing*  
8 *a participant to establish a program to collect and properly dispose*  
9 *of home-generated pharmaceutical waste. The regulations shall*  
10 *be based upon the model guidelines developed by the department*  
11 *pursuant to former Section 47122, as that section read on January*  
12 *1, 2012, shall include the requirements specified in subdivision*  
13 *(b), and shall include the provisions specified in subdivisions (c)*  
14 *and (d).*

15 *(b) The regulations adopted pursuant to this section shall*  
16 *require a participant to take all of the following actions:*

17 *(1) Provide, at no additional cost to the consumer, for the safe*  
18 *take back and proper disposal of the type or brand of*  
19 *pharmaceuticals that the participant sells or previously sold.*

20 *(2) Ensure the protection of the public health and safety, the*  
21 *environment, and the health and safety of consumers and*  
22 *employees.*

23 *(3) Report to the department, for purposes of evaluation, the*  
24 *safety, efficiency, effectiveness, and funding sustainability of the*  
25 *implemented program.*

26 *(4) Protect against the potential for the diversion of*  
27 *pharmaceutical waste for unlawful use or sale.*

28 *(5) Provide notices and materials to consumers that provide*  
29 *information about the potential impacts of improper disposal of*  
30 *home-generated pharmaceutical waste and the return opportunities*  
31 *for the proper disposal of home-generated pharmaceutical waste.*  
32 *Those materials shall include, but are not limited to, all of the*  
33 *following:*

34 *(A) Internet Web site links.*

35 *(B) Telephone numbers placed on an invoice or purchase order,*  
36 *or packaged with a pharmaceutical.*

37 *(C) Information about the opportunities and locations for*  
38 *no-cost home-generated pharmaceutical waste disposal.*

39 *(D) Signage that is prominently displayed and easily visible to*  
40 *the consumer.*

1     (E) Written materials provided to the consumer at the time of  
2     purchase or delivery.

3     (F) Reference to the home-generated pharmaceutical waste take  
4     back opportunity in advertising or other promotional materials.

5     (G) Direct communications with the consumer at the time of  
6     purchase.

7     (c) The regulations adopted pursuant to this section shall  
8     provide for all of the following:

9         (1) Specify the types of participants authorized to maintain  
10        permanent collection locations.

11       (2) Establish requirements for obtaining local or state permits  
12       or approvals.

13       (3) Require participants to enter into arrangements with medical  
14       or hazardous waste haulers, including ensuring that all  
15       home-generated pharmaceutical waste is appropriately picked up  
16       and transported by registered waste haulers.

17       (4) Specify which home-generated pharmaceutical wastes may  
18       be included in a program, including requirements for the collection  
19       of a controlled substance, as defined in Section 11007 of the Health  
20       and Safety Code.

21       (5) Specify methods for handling wastes commingled in  
22       containers with other household waste or hazardous waste.

23       (6) Provide methods for collecting and storing home-generated  
24       pharmaceutical waste, including the use of secured containers,  
25       and ensure that collected home-generated pharmaceutical waste  
26       is not resold, reused, sold, donated, or provided to anyone other  
27       than a registered medical or hazardous waste hauler.

28       (7) Provide that a facility that collects home-generated  
29       pharmaceutical waste becomes the generator of the pharmaceutical  
30       waste, and is responsible for ensuring that the storage, removal,  
31       and transportation of containers and the disposal of the waste are  
32       in compliance with state laws and regulations.

33       (8) Require the collection and retention of detailed information  
34       and invoices for each collection site.

35       (9) Impose requirements for one-time or periodic collection  
36       events.

37       (10) Impose requirements for mail-back collection and disposal  
38       programs.

39     (d) The department shall include, in the regulations adopted  
40     pursuant to this section, provisions for the appropriate

1 *management of consolidated home-generated pharmaceutical*  
2 *waste to ensure the public health and safety.*

3 *(e) The department may revise the regulations adopted pursuant*  
4 *to this article, as deemed necessary by the department, if the*  
5 *revision provides an equivalent or greater level of safety.*

6 *47122. (a) An entity that elects to implement a home-generated*  
7 *pharmaceutical waste program shall comply with the regulations*  
8 *adopted pursuant to this article.*

9 *(b) A participant operating a program in accordance with the*  
10 *regulations adopted pursuant to this article shall be deemed in*  
11 *compliance with all state laws and regulations concerning the*  
12 *handling, management, and disposal of home-generated*  
13 *pharmaceutical waste.*

14 *SEC. 5. No reimbursement is required by this act pursuant to*  
15 *Section 6 of Article XIII B of the California Constitution because*  
16 *the only costs that may be incurred by a local agency or school*  
17 *district will be incurred because this act creates a new crime or*  
18 *infraction, eliminates a crime or infraction, or changes the penalty*  
19 *for a crime or infraction, within the meaning of Section 17556 of*  
20 *the Government Code, or changes the definition of a crime within*  
21 *the meaning of Section 6 of Article XIII B of the California*  
22 *Constitution.*

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<p><b>All matter omitted in this version of the bill appears in the bill as amended in the Senate, April 1, 2014. (JR11)</b></p>
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